

CHAPTER 3
EARLY HEARING DETECTION AND INTERVENTION

EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

641—3.1(135) Definitions. For the purposes of this chapter, the following definitions will apply:

“Applicant” means a child for whom assistance under this program is being requested.

“Area education agency” or *“AEA”* means an intermediate educational unit created by Iowa Code chapter 273.

“Audiologist” means a person licensed pursuant to Iowa Code chapter 147 or certified by the Iowa board of educational examiners pursuant to 282—15.3(272) or a person appropriately licensed in the state where the person practices.

“Birth center” means *“birth center”* as defined in Iowa Code section 135.61.

“Birthing hospital” means a private or public hospital licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

“Contractor” means the entity selected by the department to act as third-party administrator for claims payment related to hearing aids and audiologic services for children.

“Department” means the Iowa department of public health.

“Diagnostic audiologic assessment” means physiologic or behavioral procedures completed by an audiologist to evaluate and diagnose hearing loss.

“Discharge” means a release from a hospital to the parent or legal guardian of the child.

“Early ACCESS” means Iowa’s Individuals with Disabilities Education Act (IDEA), Part C, program for infants and toddlers. It is a statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

“Early hearing detection and intervention advisory committee” or *“EHDI advisory committee”* means the committee appointed by the department to advise the director of the department regarding issues related to hearing health care for children and to make recommendations about the design and implementation of the early hearing detection and intervention program.

“Guardian” means a person who is not the parent of a minor child, but who has legal authority to make decisions regarding life or program issues for the child. A guardian may be a court or a juvenile court. “Guardian” does not mean conservator, as defined in Iowa Code section 633.3, although a person who is appointed to be a guardian may also be appointed to be a conservator.

“Hearing loss” means a permanent unilateral or bilateral hearing loss of greater than 30 dB HL in the frequency region important for speech recognition (500-4000 Hz).

“Hearing screening” means a physiological measurement of hearing of a newborn or infant with a “pass” or “refer” result. Screening is used to determine the newborn’s or infant’s need for further testing and must be performed bilaterally, when applicable.

“Initial screening” means a newborn hearing screening performed during the birth admission for an infant born in a birthing hospital, or the first newborn hearing screening performed on a newborn born in a facility other than a hospital.

“Newborn hearing screening” means a physiological test to separate those newborns with normal hearing from those newborns who may have hearing thresholds of greater than 30 dB HL in either ear in the frequency region important for speech recognition (500-4000 Hz).

“Normal hearing” means hearing thresholds in both ears of 30 dB HL or less in the frequency region important for speech recognition (500-4000 Hz).

“Parent” means:

1. A biological or adoptive parent of a child;
2. A guardian, but not the state if the child is a ward of the state;
3. A person acting in the place of a parent, such as a grandparent or stepparent with whom a child lives, or a person who is legally responsible for the child’s welfare;
4. A surrogate parent who has been assigned in accordance with 281—120.68(34CFR303); or

5. A foster parent, if:
 - A biological parent's authority to make the decisions required of parents under state law has been terminated; and
 - The foster parent has an ongoing, long-term parental relationship with the child; is willing to make the decisions required of a parent; and has no interest that would conflict with the interests of the child.

"Physician" means an individual licensed under Iowa Code chapter 148, 150, or 150A.

"Protocol" means a document which guides decision making and provides the criteria to be used regarding screening, diagnosis, management, and treatment of children related to hearing health care. Early hearing detection and intervention protocols not otherwise specified in this chapter are available on the department's Web site at <http://www.idph.state.ia.us/iaehdi/professionals.asp>.

"Provider" means a licensed audiologist, otolaryngologist or hearing aid dispenser who agrees to provide hearing aids or audiologic services to eligible patients.

"Rescreen" means a newborn hearing screening performed after two weeks of age on an infant who did not pass the initial screening.

"Resident" means an individual who is a legal resident of the state of Iowa.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.2(135) Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, relative to the following:

1. Universal hearing screening of all newborns and infants in Iowa.
 2. Facilitating the transfer of data to the department to enhance the capacity of agencies and practitioners to provide services to children and their families.
 3. Establishing the procedure for distribution of funds to support the purchase of hearing aids and audiologic services for children in accordance with 2009 Iowa Acts, House File 811, section 60(2) "c."
- [ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.3(135) Goal and outcomes. The goal of universal hearing screening of all newborns and infants in Iowa is early detection of hearing loss to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.4(135) Program components.

3.4(1) The early hearing detection and intervention (EHDI) coordinator assigned within the department provides administrative oversight to the early hearing detection and intervention program within Iowa.

3.4(2) The EHDI advisory committee represents the interests of the people of Iowa and assists in the development of programming that ensures the availability and access to quality hearing health care for Iowa children.

a. Committee membership includes representation from different facets of the health care community including the Iowa Hospital Association, private practice audiologists, pediatricians, family practice physicians and otolaryngologists.

b. The committee also includes representation from the deaf community, parents of children with hearing loss, advocates, Early ACCESS (IDEA, Part C), area education agencies, and other stakeholders that are affected by or involved with newborn hearing screening and follow-up.

3.4(3) The early hearing detection and intervention program has an association with the Iowa Title V maternal and child health programs to promote comprehensive services for infants and children with special health care needs.

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641—3.5(135) Screening the hearing of all newborns. All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss. The person required to perform the screening shall use at least one of the following procedures:

1. Automated or screening auditory brainstem response, or
2. Evoked otoacoustic emissions.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.6(135) Procedures required of birthing hospitals. Each birthing hospital in Iowa shall follow these procedures:

3.6(1) Each birthing hospital shall designate an employee of the hospital to be responsible for the newborn hearing screening program in that institution.

3.6(2) Prior to the discharge of the newborn, each birthing hospital shall provide hearing screening to every newborn delivered in the hospital, except in the following circumstances:

- a. The newborn is transferred for acute care prior to completion of the hearing screening.
- b. The newborn is born with a condition that is incompatible with life.

3.6(3) If a newborn is transferred for acute care, the birthing hospital shall notify the receiving facility of the status of the hearing screening. The receiving facility shall then be responsible for completion of the newborn hearing screening prior to discharge of the newborn from the nursery.

3.6(4) Newborn hearing screening shall be performed by an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician, or other person for whom newborn hearing screening is within the person's scope of practice.

3.6(5) The hospital shall report newborn hearing screening results to the parent or guardian in written form.

3.6(6) The hospital shall report newborn hearing screening results to the department in a manner prescribed in 641—3.9(135).

3.6(7) The birthing hospital shall report the results of the hearing screening to the primary care provider of the newborn or infant upon the newborn's or infant's discharge from the birthing hospital. If the newborn or infant was not tested prior to discharge, the hospital shall report the status of the hearing screening to the primary care provider of the newborn or infant.

3.6(8) The birthing hospital shall follow the hearing screening protocols prescribed by the department.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.7(135) Procedures required of birth centers. Each birth center in Iowa shall follow these procedures:

3.7(1) Each birth center shall designate an employee of the birth center to be responsible for the newborn hearing screening program in that institution.

3.7(2) Prior to discharge of the newborn, each birth center shall refer every newborn delivered in the birth center to an audiologist, physician, or hospital for a newborn hearing screening. Before discharge of the newborn, the birth center shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

3.7(3) The facility to which the newborn is referred for screening shall complete the screening within 30 days of the newborn's discharge from the birth center, unless the parent fails to attend the appointment. If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.7(4) The person who completes the newborn hearing screening shall report screening results to the parent in written form.

3.7(5) The person who completes the newborn hearing screening shall report screening results to the department in the manner prescribed in 641—3.9(135).

3.7(6) The person who completes the screening shall follow the hearing screening protocols prescribed by the department.

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641—3.8(135) Procedures to ensure that children born in locations other than a birth center or birthing hospital receive a hearing screening.

3.8(1) A physician or other health care professional who undertakes primary pediatric care of a newborn delivered in a location other than a birthing hospital or birth center shall refer the newborn to an audiologist, physician, or hospital for completion of the newborn hearing screening within three months of the newborn's birth. The health care professional who undertakes primary pediatric care of the newborn shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

3.8(2) The person who completes the newborn hearing screening shall report screening results to the parent in written form.

3.8(3) The person who completes the newborn hearing screening shall report screening results to the department in the manner prescribed in 641—3.9(135). If the parent fails to attend the appointment, the facility shall document such failure in the medical or educational record and shall report such failure to the department.

3.8(4) The person who completes the newborn hearing screening shall follow the hearing screening protocols prescribed by the department.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.9(135) Reporting hearing screening results and information to the department. Any birthing hospital, birth center, physician, audiologist or other health care professional required to report information pursuant to Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, shall report all of the following information to the department relating to each newborn's hearing screening within six working days of the birth of the newborn and within six working days of any hearing rescreen, utilizing the department's designated reporting system.

3.9(1) The name and date of birth of the newborn.

3.9(2) The name, address, and telephone number, if available, of the mother of the newborn. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

3.9(3) The name of the primary care provider for the newborn upon the newborn's discharge from the birthing hospital or birth center.

3.9(4) The results of the newborn hearing screening, either "pass," "refer," or "not screened," for each ear separately.

3.9(5) The results of any rescreening, either "pass" or "refer," and the diagnostic audiologic assessment procedures used for each ear separately.

3.9(6) Known risk indicators for hearing loss of the newborn or infant.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.10(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department. Any facility, licensed audiologist or health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results within six working days for any child under three years of age to the department utilizing the department's designated reporting system. The facility shall conduct the diagnostic hearing assessment in accordance with the Pediatric Audiologic Diagnostic Protocol contained at Appendix A. Results of a hearing screen, rescreen or diagnostic audiologic assessment shall be reported as follows.

3.10(1) Reports shall include:

- a. The name and date of birth of the child.
- b. The name, address, and telephone number, if available, of the mother of the child. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.
- c. The name of the primary care provider for the child.
- d. Known risk indicators for hearing loss.

3.10(2) Results of the newborn hearing screening shall be reported as either "pass" or "refer" for each ear separately.

3.10(3) Results of the hearing rescreen shall be reported as either “pass” or “refer” for each ear separately.

3.10(4) If an assessment results in a diagnosis of normal hearing for both ears, this shall be reported.

3.10(5) Any diagnosis of hearing loss shall also be reported except for transient conductive hearing loss lasting for less than 90 days in the professional judgment of the practitioner.

3.10(6) Diagnostic audiologic assessment results shall include a statement of the severity (mild, moderate, moderately severe, severe, profound, or undetermined) and type (sensorineural, conductive, mixed, or undetermined) of hearing loss.

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641—3.11(135) Sharing of information and confidentiality. Reports, records, and other information collected by or provided to the department relating to a child’s newborn hearing screening, rescreen, and diagnostic audiologic assessment are confidential records pursuant to Iowa Code section 22.7.

3.11(1) Personnel of the department shall maintain the confidentiality of all information and records used in the review and analysis of newborn hearing screenings, rescreens, and diagnostic audiologic assessments, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

3.11(2) No individual or organization providing information to the department in accordance with this rule shall be deemed to be or held liable for divulging confidential information.

3.11(3) The department shall not release confidential information except to the following persons and entities under the following conditions:

- a. The parent or guardian of an infant or child for whom the report is made.
- b. A local birth-to-three coordinator with the Early ACCESS program or an agency under contract with the department to administer the children with special health care needs program.
- c. A local health care provider.
- d. A representative of a federal or state agency, to the extent that the information is necessary to perform a legally authorized function of that agency.
- e. A representative of a state agency, or an entity bound by that state, to the extent that the information is necessary to perform newborn hearing screening follow-up. The state agency or the entity bound by that state shall be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa. The state agency or the entity bound by that state shall not use the information obtained from the department to market services to patients or nonpatients or identify patients for any purposes other than those expressly provided in this rule.

3.11(4) Research purposes. All proposals for research using the department’s data to be conducted by persons other than program staff shall first be submitted to and accepted by the researchers’ institutional review board. Proposals shall then be reviewed and approved by the department before research can commence.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.12(135) Reporting requirements for AEAs. Rescinded IAB 10/7/09, effective 11/11/09.

641—3.13(135) Procedure to accommodate parental objection. These rules shall not apply if the parent objects to the hearing screening.

3.13(1) If a parent objects to the screening, the birthing hospital, birth center, physician, or other health care professional shall obtain a written refusal from the parent or guardian on the department newborn hearing screening refusal form and shall maintain the original copy of the written refusal in the newborn’s or infant’s medical record.

3.13(2) The birthing hospital, birth center, physician, or other health care professional shall send a copy of the written newborn hearing screening refusal form to the department within six days of the birth of the newborn.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.14(135) Civil/criminal liability. A person who acts in good faith in complying with these rules shall not be held civilly or criminally liable for reporting the information required.
[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.15() and 3.16() Reserved

HEARING AIDS AND AUDIOLOGIC SERVICES FUNDING PROGRAM

641—3.17(83GA,HF811) Eligibility criteria. The enrollment process to determine eligibility for services under this program includes the following requirements:

3.17(1) Age. Individuals are eligible from birth through 20 years of age.

3.17(2) Residency. Individuals must currently reside in Iowa.

3.17(3) The applicant must not be eligible for hearing aids or audiologic services under Title XIX or HAWK-I.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.18(83GA,HF811) Covered services.

3.18(1) Funding does not cover either the surgical costs associated with a cochlear or Baha implant or the cost of the devices.

3.18(2) Funding does not pay for services denied by insurance because the applicant received services outside the provider network.

3.18(3) The following hearing aids and audiologic services may be provided through the hearing aids and audiologic services funding program:

1. Repair/modification of hearing aid
2. Hearing aid, monaural, behind the ear
3. Hearing aid dispensing fee, monaural
4. Hearing aid, binaural, in the ear
5. Hearing aid, binaural, behind the ear
6. Hearing aid dispensing fee, binaural
7. Hearing aid, bicros, glasses
8. Ear mold/insert, not disposable, any type
9. Battery for use in hearing aid
10. Hearing aid supplies, accessories
11. Assistive listening device, not otherwise specified
12. Assistive listening device, dispensing
13. Service handling charge
14. Service charge, ear mold
15. Annual charge, ear mold
16. Pure tone audiometry, air only
17. Pure tone audiometry, air and speech audiometry threshold
18. Speech audiometry threshold
19. Speech audiometry threshold with speech
20. Comprehensive audiometry threshold evaluation
21. Tympanometry (impedance testing)
22. Conditioning play audiometry
23. Auditory-evoked potentials for evoked response audiometry, comprehensive
24. Auditory-evoked potentials for evoked response audiometry, limited
25. Visual reinforcement audiometry
26. Evoked otoacoustic emissions, limited
27. Hearing aid examination and selection, monaural
28. Hearing aid examination and selection, binaural
29. Hearing aid check, monaural
30. Hearing aid check, binaural

31. Electroacoustic evaluation for hearing aid, monaural
32. Electroacoustic evaluation for hearing aid, binaural
33. Office/outpatient visit related to audiologic services
34. Consultations related to audiologic services

3.18(4) The department may elect to cover additional services not otherwise restricted in these rules.
[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.19(83GA, HF811) Application procedures.

3.19(1) A child, or the parent or guardian of a child, desiring hearing aids or audiologic services may apply to the contractor.

3.19(2) The following information shall be provided to the contractor by the applicant to be considered for eligibility under this program:

- a. Patient's first name, middle initial and last name.
- b. Patient's date of birth.
- c. Patient's address, including city, state and ZIP code.
- d. Parent/guardian's first name, middle initial and last name.
- e. Parent/guardian's telephone number.
- f. Parent/guardian's E-mail address.
- g. Parent/guardian's or child's medical insurance plan name.
- h. Hearing aid/audiologic service provider name and telephone number.
- i. Whether the request is for hearing aids or audiologic services or both.
- j. Estimated service costs.

3.19(3) Applicants will be enrolled in the program on a first-come, first-served basis upon the date the application is received by the contractor.

3.19(4) The contractor will provide written notification to the applicant regarding determination of eligibility or noneligibility and the applicant's right to appeal a denial. For those applicants deemed eligible, an enrollee number will be assigned by the contractor.

3.19(5) An applicant must submit a renewal application form on an annual basis, accompanied by all information requested by the department.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.20(83GA, HF811) Hearing aids and audiologic services funding wait list.

3.20(1) If an applicant is eligible for hearing aid and audiologic services funding and sufficient funds are available to provide services to the applicant, the contractor shall enroll the applicant upon approval by the department. If the applicant is eligible for hearing aid and audiologic services funding and sufficient funds are not available to provide services to the applicant, the contractor upon approval by the department shall place the applicant's name on the hearing aid and audiologic services funding wait list in the order provided for in this rule.

3.20(2) The contractor, upon approval by the department, shall place names on the wait list in the following order:

- a. Applicants under the age of three diagnosed with a hearing loss who are in need of hearing aids.
- b. Applicants in need of hearing aids or audiologic services.
- c. All other applicants, who shall be placed on the wait list in chronological order based upon the

date of receipt of a completed application by the contractor upon approval by the department.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.21(83GA, HF811) Reimbursement of providers.

3.21(1) To receive reimbursement for hearing aids and audiologic services, the provider must complete a provider information sheet and I-9 form provided by the department.

3.21(2) The provider must be a Title XIX provider.

3.21(3) Reimbursement of hearing aids and audiologic services will be paid directly to the provider based on Title XIX reimbursement rates.

- a. Bills will be adjusted accordingly by the department prior to payment.

b. Reimbursement for hearing aids or supplemental hearing devices includes the costs of shipping and handling.

3.21(4) Hearing aids and audiologic services funding shall be the payor of last resort.

3.21(5) Payment through this funding source is considered payment in full for covered services. If a third party liability (TPL) payment equals or exceeds the Title XIX allowance, no further reimbursement is provided.

3.21(6) The provider shall submit bills after an enrollee number is assigned to the applicant and the audiologic service is provided or hearing aid is fitted.

3.21(7) The provider shall submit the following documents:

a. Health Care Financing Administration Form HCFA 1500. Forms will be furnished by the providers and will include the applicant's enrollee number in the upper right-hand corner of the form.

b. Manufacturer's invoice for hearing devices as prescribed by the department.

c. Applicant's explanation of benefits or documentation of a telephone contact made by the provider to the patient's private insurance company including: date of contact, name of insurance representative, name of insurance company, applicant's policy number and coverage limitations for hearing evaluations and devices.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

641—3.22(83GA, HF811) Appeals. The department shall cause an applicant to be notified of the department's decision to approve or deny an application or to place an applicant on the child hearing aids and audiologic services wait list. In the event an applicant is dissatisfied with the department's decision, the applicant may submit a formal appeal in writing to the EHDI advisory committee. Such request shall be delivered in person or shall be mailed by certified mail, return receipt requested, to EHDI Advisory Committee, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319. Upon receipt of such an appeal, the EHDI advisory committee shall review the case and issue a written determination within 15 days of receipt of the request. The decision shall refer to the applicant by initials or other nonidentifying means. The EHDI advisory committee's decision shall be final and binding. This appeal process does not constitute a contested case proceeding as defined in Iowa Code chapter 17A.

[ARC 8232B, IAB 10/7/09, effective 11/11/09]

These rules are intended to implement Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, and 2009 Iowa Acts, House File 811, division IV, section 60(2) "c."

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Appendix A

Pediatric Audiologic Diagnostic Protocol

The following protocol should be used to facilitate the diagnosis of hearing loss by three months of age and entry into early intervention for infants with hearing loss by six months of age. This diagnostic protocol should be implemented by an audiologist licensed by the Iowa board of speech pathology and audiology examiners or certified by the Iowa board of educational examiners.

Infants should be referred for a diagnostic evaluation after receiving a “refer” result from one or both ears on a newborn hearing screening and a hearing rescreen performed at two to six weeks of age. Timely referral for diagnostic auditory brainstem response (ABR) testing may negate the need for sedation for this test in very young infants. Infants who are identified at risk for congenital or late-onset hearing loss (JCIH, 2007) should receive an audiologic assessment at least once by 24 to 30 months of age. Children with risk indicators that are highly associated with late-onset hearing loss, such as having received ECMO or having congenital CMV infection, should have more frequent audiologic assessments based on infant or toddler needs. All infants for whom the family has significant concerns regarding hearing or communication should be promptly referred for an audiologic and speech-language assessment.

Audiologic diagnostic centers should be prepared to provide the following services:

I. Measures of auditory sensitivity

A. Auditory brainstem response (ABR)

Infants who do not pass the newborn hearing screening or rescreen should be evaluated with a click-evoked air-conduction ABR and at least one low-frequency tone burst ABR, preferably at 500 Hz. Response waveforms should be measured at several levels to allow threshold determination and latency-intensity functions. When thresholds are determined to be elevated, the audiologist may measure the ABR with frequency-specific stimuli at other frequencies as well. Infants suspected of having significant conductive hearing loss should be considered for bone-conduction ABR testing. Clinicians should be aware that technological advances will continually improve recommended protocols.

B. Evoked otoacoustic emissions

Transient evoked otoacoustic emissions (TEOAE) or distortion product otoacoustic emissions (DPOAE) should be used to confirm the magnitude and configuration of the hearing loss as determined by the ABR.

C. Behavioral measures

At a developmental age of six months or older, it is possible to obtain reliable behavioral audiometric information using visual reinforcement audiometry (VRA). While this test has traditionally been performed in the sound field, ear-specific threshold information can be obtained using insert earphones. VRA is an important technique for use in monitoring auditory thresholds, especially during the first few years of hearing aid use.

II. Measures of middle ear function

A. Tympanometry

Although pass/fail criteria for tympanograms from infants younger than six months of age are currently being developed, an infant audiologic evaluation should include an admittance tympanogram at 1000 Hz to help determine middle ear function.

B. Acoustic reflexes

Ipsilateral or contralateral acoustic reflexes should be measured at a minimum of two activator frequencies (1000 and 2000 Hz) at a probe tone of 800 or 1000 Hz.